- 277. As a proximate result of the fraud and deceit of Wyeth and its predecessors, Plaintiff sustained the injuries and damages as described in this Complaint.
- 278. As a proximate result of the fraud and deceit of Schwarz, Plaintiff sustained the injuries and damages as described in this Complaint.
- 279. Defendant Schwarz breached its duty as the NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, because it misrepresented the safety of Reglan, metoclopramide and metoclopramide HCl, and withheld warnings of the known side effects of the drug as commonly prescribed by physicians when it knew or should have known of the safety issues surrounding Reglan, metoclopramide and metoclopramide HCl.
- Because Defendant Schwarz acquired Defendant Wyeth's Reglan, metoclopramide and metoclopramide HCl, assets and liabilities, while Wyeth was involved in ongoing litigation regarding Reglan, metoclopramide and metoclopramide HCl, and nevertheless agreed to indemnify Wyeth against all claims related to the ingestion of Reglan, metoclopramide and metoclopramide HCl, Schwarz knew or should have known that the NDA label for Reglan, metoclopramide and metoclopramide HCl (Wyeth's label) misrepresented the safety of Reglan, metoclopramide and metoclopramide HCl; withheld warnings of the known side effects of the drug; and knew or should have known of the safety issues surrounding Reglan, metoclopramide and metoclopramide HCl.
- 281. Defendant Schwarz breached its duty to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, because it intentionally and fraudulently made statements to defraud and deceive the medical community, Plaintiff, and other foreseeable users of this drug, and Plaintiff's physician, with the intent to induce practitioners to use Reglan/metoclopramide as pharmaceutical treatment for diabetic gastropaeries for a period of time that far exceeded the FDA's approved indicated

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- As set forth above, Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, and its predecessors falsely and fraudulently represented to physicians, Plaintiff's physicians, and to foreseeable users, including Plaintiff, that the drug was safe to use in the treatment of diabetic gastropaeries and that permanent neurological side effects were comparatively rare. These representations were, in fact, false. The true facts were that Reglan/metoclopramide was not safe for that purpose and was, in fact, dangerous to the health and body of Plaintiff.
- Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors did not disclose or warn physicians about the actual prevalence of known side effects of Reglan/metoclopramide, particularly when Reglan/metoclopramide is used on a *long term basis*, as marketed by Wyeth *and/or* Schwarz, or when used in patients who are poor metabolizers of metoclopramide, all of which were foreseeable.
- 284. Schwarz did not disclose or warn physicians about the true risks and prevalence of known side extrapyramidal side effects of Reglan/metoclopramide, particularly when Reglan/metoclopramide is used on a *long term basis*, by diabetics, all of which were foreseeable.
- 285. At the time Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors made the above described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.
- 286. In reliance upon the representations of Schwarz as the NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors Plaintiff's physicians were induced to and did prescribe Plaintiff Reglan,

- CASE 0:07-cv-03919-DWF-SER Document 1-1 Filed 09/07/07 Page 3 of 47 metoclopramide and/or metoclopramide HCl.
- 287. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Schwarz's breach of its duty as an NDA holder and/or Referenced Listed Drug Company of Reglan, metoclopramide and metoclopramide HCl, and manufacturer, in failing to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Reglan, metoclopramide and/or metoclopramide HCl.
- 288. In doing the acts alleged in this Complaint, Schwarz acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Schwarz and others from engaging in similar conduct in the future.
- 289. As a proximate result of the fraud and deceit of Schwarz and its predecessors in interest,

 Plaintiff sustained the injuries and damages as described in this Complaint.
- 290. Wyeth and Schwarz had actual knowledge of facts which demonstrated that representations in the Reglan, metoclopramide and metoclopramide HCl package insert, PDR monograph and literature that they distributed concerning Reglan, metoclopramide and metoclopramide HCl to physicians was false and misleading.
- 291. Wyeth had an absolute duty to disclose the true facts regarding the safety of Reglan, metoclopramide and metoclopramide HCl to the medical community, to physicians and their patients, pharmacists, and the generic metoclopramide industry, which they negligently and/or intentionally failed to do.
- 292. Schwarz had an absolute duty to disclose the true facts regarding the safety of Reglan, metoclopramide and metoclopramide HCl to the medical community, to physicians and their patients, pharmacists, and the generic metoclopramide industry, which it negligently

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- 293. Wyeth had a duty to ensure that it had a reasonable basis for making the representations regarding the safety, efficacy, risks and benefits of Reglan, metoclopramide and metoclopramide HCl, were accurate and was under at duty to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which it negligently and/or intentionally failed to do.
- 294. Schwarz had a duty to ensure that it had a reasonable basis for making the representations regarding the safety, efficacy, risks and benefits of Reglan, metoclopramide and metoclopramide HCl, were accurate and was under at duty to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which it negligently and/or intentionally failed to do.
- 295. Wyeth and Schwarz failed to report important information and data relating to Reglan, metoclopramide and metoclopramide HCl risks, side effects and prevalence of extrapyramidal side effects, which information was in the exclusive control of Wyeth and Schwarz and was exclusively known by them, and thus breached their duty to the medical community, Plaintiff's Physician, Plaintiff and other like foreseeable users, and thereby putting Plaintiff and other like foreseeable users at harm.
- 296. To further its own profits and interests, Wyeth disseminated false and misleading information regarding the safety and efficacy of Reglan, metoclopramide and metoclopramide HCl to the medical community, Plaintiff's physician, pharmacists, Plaintiff and other like foreseeable users, and did so knowing that the safety of metoclopramide users depended on the accuracy of that information.
- 297. To further its own profits and interests, Schwarz disseminated false and misleading information regarding the safety and efficacy of Reglan, metoclopramide and metoclopramide HCl to the medical community, Plaintiff's physician, pharmacists,

Plaintiff and other like foreseeable users, and did so knowing that the safety of metoclopramide users depended on the accuracy of that information.

- 298. Wyeth knew and expected the medical community, physicians, pharmacists, Plaintiff's physician, Plaintiff and other like foreseeable users of Reglan, metoclopramide and metoclopramide HCL, would rely on the information Wyeth disseminated, that said individuals would take action based upon that information, and that Plaintiff and other like foreseeable users who ingested said drug would be put in peril by Wyeth's dissemination of false and misleading information and would suffer physical harm as a result.
- 299. Schwarz knew and expected the medical community, physicians, pharmacists, Plaintiff's physician, Plaintiff and other like foreseeable users of Reglan, metoclopramide and metoclopramide HCL, would rely on the information Schwarz disseminated, that said individuals would take action based upon that information, and that Plaintiff and other like foreseeable users who ingested said drug would be put in peril by Schwarz's dissemination of false and misleading information and would suffer physical harm as a result.
- 300. Wyeth expressly and/or impliedly represented to the medical community, physicians, pharmacists, Plaintiff's physician, Plaintiff and other like foreseeable users that Reglan/metoclopramide was safe for long term use and that the risk of developing a severe neurological movement disorder was "rare" when in fact long term use significantly increases a patient's risk of contracting said disorder.
- 301. Schwarz expressly and/or impliedly represented to the medical community, physicians, pharmacists, Plaintiff's physician, Plaintiff and other like foreseeable users that Reglan/metoclopramide was safe for long term use and that the risk of developing a severe neurological movement disorder was "rare" when in fact long term use

- CASE 0:07-cv-03919-DWF-SER Document 1-1 Filed 09/07/07 Page 6 of 47 significantly increases a patient's risk of contracting said disorder.
- 302. Wyeth and Schwarz falsely misrepresented that Reglan, metoclopramide and metoclopramide HCl was safe for long term use even though it *did not* conduct any studies regarding long term use; failed to present accurate or sufficient information concerning these truth of these representations; and failed to exercise reasonable care in disseminating accurate and truthful information regarding long term use.
- 303. Wyeth's misrepresentations or omissions were made to the medical community, physicians across the nation, Plaintiff's physician, Plaintiff, Plaintiff's pharmacists, the generic pharmaceutical industry and foreseeable users of the drug, all of whom justifiably and foreseeably relied on those representations or omissions.
- 304. Schwarz's misrepresentations or omissions were made to the medical community, physicians across the nation, Plaintiff's physician, Plaintiff, Plaintiff's pharmacists, the generic pharmaceutical industry and foreseeable users of the drug, all of whom justifiably and foreseeably relied on those representations or omissions.
- 305. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Wyeth.
- 306. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Schwarz.
- 307. Wyeth's misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.
- 308. Schwarz's misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.
- 309. At all times mentioned in this Complaint, Wyeth and its predecessors had the duty and obligation to disclose to the medical community, Physicians, Plaintiff's physicians, Plaintiff and other like foreseeable users, the true facts concerning true level of risk

- CASE 0:07-cv-03919-DWF-SER Document 1-1 Filed 09/07/07 Page 7 of 47 involved in prescribing Reglan/metoclopramide for the purposes indicated.
- 310. Wyeth and its predecessors made the affirmative representations set forth above to Plaintiff, Plaintiff's prescribing physicians, and the general public prior to the day Plaintiff was first prescribed and used Reglan/ metoclopramide while concealing the material facts regarding the safety and efficacy of said drug.
- 311. At all times mentioned in this Complaint, Schwarz had the duty and obligation to disclose to the medical community, Physicians, Plaintiff's physicians, Plaintiff and other like foreseeable users, the true facts concerning true level of risk involved in prescribing Reglan, metoclopramide and metoclopramide HCl associated with long term use.
- 312. Schwarz made the affirmative representations set forth above to the medical community, physicians, Plaintiff, Plaintiff's physicians, and other foreseeable users, prior to the day Plaintiff was first prescribed and used Reglan/ metoclopramide while concealing the material facts regarding the safety and efficacy of said drug.
- 313. Wyeth and its predecessors had the duty and obligation, to disclose to the medical community, Physicians, Plaintiff's physician, Plaintiff and other like foreseeable users, the true facts concerning Reglan/ metoclopramide that is that long term use and exposure could cause central nervous system side effects, including but not limited to, akathesia, akinesia, tardive dyskinesia and tardive dystonia.
- 314. Schwarz and its predecessors had the duty and obligation, to disclose to the medical community, Physicians, Plaintiff's physician, Plaintiff and other like foreseeable users, the true facts concerning Reglan/ metoclopramide that long term use and exposure could cause central nervous system side effects, including but not limited to, akathesia, akinesia, tardive dyskinesia and tardive dystonia.
- 315. Wyeth and its predecessors intentionally, willfully and maliciously concealed or suppressed the risks and prevalence of extrapyramidal side effects associated with the

- long term use of this drug, from the medical community, physicians, Plaintiff's physicians, and therefore from Plaintiff, and other like foreseeable users, with the intent to defraud as alleged in this Complaint.
- 316. Plaintiff nor Plaintiff's physicians were aware of the facts set forth above. Had they been aware of those facts, they would not have acted as they did, that is, would not have utilized Reglan, metoclopramide and metoclopramide HCl in the treatment of Plaintiff's diabetic gastroparesis for periods of time that exceeded 12 weeks duration.
- 317. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff was prescribed and took Reglan/metoclopramide and subsequently contracted a severe permanent neurological disorder, thereby sustaining the injuries and damages as set forth in this Complaint.
- 318. In doing the acts alleged in this Complaint, Wyeth and its predecessors acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to Wyeth's wealth, and sufficiently large to be an example to others and to deter Wyeth and others from engaging in similar conduct in the future.
- 319. At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and prepare for use and sell Reglan, metoclopramide and metoclopramide HCl.
- 320. At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS had a duty to truthfully, accurately and fully disclose information and data which would reflect that the risks of extrapyramidal side effects clearly outweighed the utility of the Reglan, metoclopramide, and/or metoclopramide HCl or its therapeutic benefits to patients, specifically, elderly female diabetic patients.

- 321. At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS manufactured, compounded, tested, inspected, packaged, labeled, distributed, marketed, examined, maintained, supplied, provided warnings, and prepared for use and sold Reglan, metoclopramide and metoclopramide HCl.
- 322. The DRUG COMPANY DEFENDANTS knew or should have known that use of metoclopramide created an unreasonable risk as a result of its design, testing, and/or manufacturing, including an unreasonable risk of central nervous system side effects, including but not limited to, depression, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and/or interference with drug metabolism.
- 323. The DRUG COMPANY DEFENDANTS knew or should have known that use of metoclopramide created an unreasonable risk as a result of its design, testing, and/or manufacturing, including an unreasonable risk of central nervous system side effects, including but not limited to, depression, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and/or interference with drug metabolism in elderly female diabetic patients.
- 324. The DRUG COMPANY DEFENDANTS were negligent, and breached their duties owed to the medical community, Physicians, Plaintiff's physician, Plaintiff and other like foreseeable users, with respect to Reglan, metoclopramide and metoclopramide HCl in one or more of the following respects:
 - (a) Despite knowledge of hazards and knowledge that the Reglan, metoclopramide, and metoclopramide HCl was frequently prescribed for long term use, they failed to accompany the Reglan, metoclopramide, and/or metoclopramide HCl with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of metoclopramide and particularly with foreseeable long term use;
 - (b) They failed to conduct adequate testing;
 - (c) Despite knowledge of hazards, they failed to conduct adequate postmarketing surveillance to determine the safety of the Reglan, metoclopramide, and/or metoclopramide HCl;

- (d) Despite knowledge of hazards, they failed to adequately warn Plaintiff's physicians or Plaintiff that the use of metoclopramide could result in serious side effects, including but not limited to depression with suicidal ideation, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and interferences with drug metabolism; and
- (e) Despite the fact that the Drug Company Defendants knew or should have known that metoclopramide caused unreasonably dangerous side effects, they failed to adequately disclose the known or knowable risks associated with Reglan, metoclopramide and metoclopramide HCl and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other foreseeable users of Reglan, metoclopramide and metoclopramide HCl.
- (f) Despite the fact that the Drug Company Defendants knew or should have known that metoclopramide caused unreasonably an increased risk of extrapyramidal side effects to elderly female diabetic patients, they failed to adequately disclose the known or knowable risks associated with Reglan, metoclopramide and metoclopramide HCl and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other like foreseeable users of Reglan, metoclopramide and metoclopramide HCl.
- 325. As a result of the negligence of the DRUG COMPANY DEFENDANTS and their willful and wanton misconduct, Reglan, metoclopramide and/or metoclopramide HCl was prescribed to Plaintiff for long term use and was used as prescribed, thereby causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.
- 326. The negligence and the willful and wanton misconduct of the DRUG COMPANY DEFENDANTS was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer.
- 327. At all times mentioned in this Complaint, metoclopramide was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the DRUG COMPANY DEFENDANTS.

- 328. Reglan, metoclopramide and metoclopramide HCL was "defective" and "unreasonably dangerous" when the drug was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:
 - (a) At the time metoclopramide left the control of the DRUG COMPANY DEFENDANTS it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the Reglan, metoclopramide, and/or metoclopramide HCl breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.
 - (b) Metoclopramide was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the Reglan, metoclopramide, and/or metoclopramide HCl left the possession of the DRUG COMPANY DEFENDANTS, and that such risks clearly outweighed the utility of the Reglan, metoclopramide, and/or metoclopramide HCl or its therapeutic benefits.
 - (c) At the time metoclopramide left the control of the DRUG COMPANY DEFENDANTS it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the Reglan, metoclopramide, and/or metoclopramide HCl left the possession of the DRUG COMPANY DEFENDANTS. Specifically, although the DRUG COMPANY DEFENDANTS were well aware that metoclopramide could potentially cause central nervous system side effects, including but not limited to, depression with suicidal ideation, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with the metabolism of other prescription drugs and in fact, had significantly greater prevalence and severity of these side effects in patients with diabetes mellitus, warnings of such adverse health conditions were either not included on the package insert for these Reglan, metoclopramide, and/or metoclopramide HCl or they were not adequate to inform reasonably prudent physicians and foreseeable users. The DRUG COMPANY DEFENDANTS failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of metoclopramide.
 - (d) The DRUG COMPANY DEFENDANTS' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the Reglan, metoclopramide, and/or metoclopramide HCl taking into account the characteristics of the Reglan, metoclopramide, and/or metoclopramide HCl, and/or the ordinary

- knowledge common to the physician who prescribes and the consumer who purchases the Reglan, metoclopramide, and/or metoclopramide HCl, such as the Plaintiff.
- (e) The metoclopramide manufactured and supplied by the DRUG COMPANY DEFENDANTS was further defective due to inadequate post-marketing warning or instruction because, after the DRUG COMPANY DEFENDANTS knew or should have known of the risks of injury from Metoclopramide associated with long term use as commonly prescribed, they failed to promptly respond to and adequately warn about extrapyramidal side effects to foreseeable users.
- (f) The metoclopramide manufactured and supplied by the DRUG COMPANY DEFENDANTS was further defective due to inadequate post-marketing warning or instruction because, after the DRUG COMPANY DEFENDANTS knew or should have known of the risks of injury from Reglan/metoclopramide and/or metoclopramide HCl associated with long term use as commonly prescribed, they failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for elderly patients for permanent neuological movement disorders, particularly the risk associated with the long term use of Reglan, metoclopramide, and/or metoclopramide HCl posed to diabetic patients, who were foreseeable users of the drug.
- The DRUG COMPANY DEFENDANTS, individually and collectively, knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.
- 330. A reasonably competent physician who prescribed metoclopramide and a reasonably competent Plaintiff who consumed metoclopramide would not realize its dangerous condition.
- The DRUG COMPANY DEFENDANTS, individually and collectively, knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of metoclopramide that caused the damages for which Plaintiff seeks recovery.
- The reasonably foreseeable use of metoclopramide, that is ingestion as treatment for diabetic gastroparesis on a long term basis, involved substantial dangers not readily recognizable by Plaintiff's physician, who acted as an ordinary reasonable

and prudent physicians would, when prescribing metoclopramide to an ordinary, reasonable and prudent patient, like Plaintiff.

- 333. The DRUG COMPANY DEFENDANTS knew that the Reglan, metoclopramide and metoclopramide HCl which was to be prescribed by physicians and used by foreseeable users without inspection for defects in the Reglan, metoclopramide, and/or metoclopramide HCl or in any of its components or ingredients and that metoclopramide was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.
- Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of metoclopramide, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.
- These defects caused serious injuries to Plaintiff when the Reglan, metoclopramide, and/or metoclopramide HCl was used in its intended and foreseeable manner, and in the manner recommended by the DRUG COMPANY DEFENDANTS or in a non-intended manner that was reasonably foreseeable.
- Defendant Wyeth's predecessor in interest, A.H. Robins Company, Inc. expressly warranted to some physicians that Reglan/metoclopramide is safe in long-term use.
- A.H. Robins knew that is its warranties regarding safety for long term use, would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their community and that eventually physicians would come to rely on A.H. Robins' express warranties about Reglan/metoclopramide's safety in long-term use.
- 338. A.H. Robins' express warranties about the safety of Reglan/metoclopramide in long-term use were false and intentionally and/or negligently misleading.

- As successor in interest to A.H. Robins Company, Inc., Wyeth is legally responsible for the conduct, fraudulent and negligent acts and/or intentional and willful omissions and/or misleading representations and warranties made by A.H. Robins Company, Inc., concerning the safety and adequacy of Reglan/metoclopramide, and liable for injuries which may result therefrom.
- 340. PLIVA is legally responsible for the conduct, fraudulent and negligent acts and/or intentional and willful omissions and/or misleading representations and warranties made by PLIVA and/or parent corporation, Pliva d.d., concerning the safety and adequacy of Reglan/metoclopramide and/or metoclopramide HCl and liable for injuries which may result therefrom.
- As successor in interest to Purepac, Defendant Alpharma, is legally responsible for the conduct, fraudulent and negligent acts and/or intentional and willful omissions and/or misleading representations and warranties made by, concerning the safety and adequacy of Reglan/metoclopramide, and liable for injuries which may result therefrom.
- The DRUG COMPANY DEFENDANTS knew that most physicians who prescribed metoclopramide were not aware the drug is a dopamine antagonist and/or a neuroleptic agent, which is just as likely to cause serious extrapyramidal side effects as other dopamine antagonists and/or other neuroleptic drugs.
- 343. The DRUG COMPANY DEFENDANTS also knew that the risks of potentially irreversible neurological side effects when metoclopramide is used long term were much greater than most physicians realized. By failing to give adequate warnings about the dopamine antagonist and/or neuroleptic properties of metoclopramide and the risk of long term use that is associated with those properties, the DRUG COMPANY DEFENDANTS breached implied warranties of merchantability and

fitness for the ordinary use of metoclopramide.

- At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold metoclopramide and prior to the time it was used by Plaintiff, the DRUG COMPANY DEFENDANTS impliedly warranted to Plaintiff and to Plaintiff's physicians that the Reglan, metoclopramide, and/or metoclopramide HCl was of merchantable quality and safe and fit for the use for which it was intended.
- Plaintiff relied on the skill and judgment of the DRUG COMPANY

 DEFENDANTS in using metoclopramide as prescribed.
- Metoclopramide was unsafe and unfit for its intended use, nor was it of merchantable quality, as warranted by the DRUG COMPANY DEFENDANTS, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. Metoclopramide was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, the drug proximately caused Plaintiff to sustain damages and injuries as alleged in this Complaint by virtue of causing Plaintiff's illness.
- 347. By virtue of their individual and collective acts and omissions, Defendants are jointly and severally liable to Plaintiff as such acts and omissions have proximately caused Plaintiff to suffer a single indivisible injury for which each Defendant is responsible.
- Plaintiff is entitled to recovery an award for the injuries caused by the DRUG COMPANY Defendants.

- 349. As a direct and proximate result of the aforesaid acts of and/or omissions by the DRUG COMPANY Defendants, individually and jointly, Plaintiff, has:
 - (a) suffered severe and permanent injuries, which she will be forced to endure for the remainder of Plaintiff's life;
 - (b) suffered physical impairment and disfigurement;
 - (c) suffered physical pain and suffering;
 - (d) suffered mental pain and suffering;
 - (e) had Plaintiff's enjoyment of life severely impaired; incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiff's injuries; and incurred attorney's fees and expenses of litigation related to this action.
- 350. DRUG COMPANY Defendants actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to Plaintiff.

V. WRONGFUL CONDUCT

COUNT 1

STRICT PRODUCTS LIABILITY

- 351. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 352. At all relevant times the DRUG COMPANY DEFENDANTS were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling metoclopramide.
- 353. Drug Company defendants, developed, marketed and distributed Reglan, metoclopramide and/or metoclopramide HCl to the general public even after learning of the design and manufacturing defects that threatened the intended use of the drug.

- 354. Reglan, metoclopramide and/or metoclopramide HCl was defective and unreasonably dangerous and was expected to and did reach Plaintiff without substantial change in the drug.
- 355. At all times mentioned in this Complaint, metoclopramide was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the DRUG COMPANY DEFENDANTS.
- 356. Drug company defendants knew or should have known through testing, adverse event reporting, or otherwise, that the drug created a high risk of bodily injury and serious harm.
- 357. The dangerous propensities of Reglan, metoclopramide and/or metoclopramide HCl products, were known or scientifically knowable, through appropriate research and testing, to the DRUG COMPANY DEFENDANTS at the time said Defendants distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients, or their patients.
- 358. The Reglan, metoclopramide and/or metoclopramide HCl products, as distributed by the DRUG COMPANY DEFENDANTS, were defective and unreasonably dangerous inasmuch as they were not accompanied by warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for long term Reglan, metoclopramide and/or metoclopramide HCl therapy.
- 359. Prior to the manufacturing, sale and distribution of said drug products, DRUG COMPANY DEFENDANTS, and each of them, knew that said drug products were in a defective condition as previously described, and knew that said drug products were in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.
- 360. DRUG COMPANY DEFENDANTS, and each of them, through their officers, directors and managing agents, had prior notice and knowledge from several sources, prior to the date of

- dispensing of said drug products to Plaintiff, that the drugs presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drugs were unreasonably subjected to risk of injury or death from the consumption of said drugs.
- 361. Despite such knowledge, DRUG COMPANY DEFENDANTS, and each of them, acting through their officers, directors and managing agents, for the purpose of enhancing DRUG COMPANY DEFENDANTS' profits, knowingly and deliberately failed to warn the public, including Plaintiff, of the extreme risk of physical injury occasioned by said defects inherent in said drugs. DRUG COMPANY DEFENDANTS intentionally proceeded with the manufacturing, the sale and distribution, and marketing of the drugs with knowledge that consumers would be exposed to serious danger in order to advance DRUG COMPANY DEFENDANTS own pecuniary interest.
- 362. The Reglan, metoclopramide and/or metoclopramide HCl products, as distributed by the DRUG COMPANY DEFENDANTS, were defective and unreasonably dangerous inasmuch as they were not accompanied by warnings and instructions that were appropriate and adequate to render the products reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for long term Reglan, metoclopramide and/or metoclopramide HCl therapy.
- 363. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, Reglan, metoclopramide and/or metoclopramide HCl, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by DRUG COMPANY DEFENDANTS through third parties or related entities.
- 364. Reglan/metoclopramide was "defective" and "unreasonably dangerous" when the product initially was patented, and subsequently when it was promoted and entered into the stream of

commerce and was received by Plaintiff, in one or more of the following respects:

- (a) At the time metoclopramide left the control of the DRUG COMPANY DEFENDANTS it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the product breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.
- (b) Metoclopramide was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the DRUG COMPANY DEFENDANTS, and that such risks clearly outweighed the utility of the product or its therapeutic benefits.
- At the time metoclopramide left the control of the DRUG COMPANY (c) DEFENDANTS it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the DRUG COMPANY DEFENDANTS. Specifically, although the DRUG COMPANY DEFENDANTS were well aware that metoclopramide could potentially cause central nervous system side effects, depression with suicidal ideation, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with the metabolism of other prescription drugs and in fact, had significantly greater prevalence and severity of these side effects in patients with diabetes mellitus, warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform reasonably prudent physicians and consumers. The DRUG COMPANY DEFENDANTS failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of metoclopramide.
- (d) The DRUG COMPANY DEFENDANTS' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the product, such as the Plaintiff.
- (e) The metoclopramide manufactured and supplied by the DRUG COMPANY DEFENDANTS was further defective due to inadequate post-marketing warning or instruction because, after the DRUG COMPANY DEFENDANTS knew or should have known of the risks of injury from Metoclopramide associated with long term use as commonly prescribed, they failed to promptly respond to and adequately warn about extrapyramidal side effects, among other adverse reactions.

- 365. The DRUG COMPANY DEFENDANTS knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery. A reasonably competent physician who prescribed metoclopramide and a reasonably competent Plaintiff who consumed metoclopramide would not realize its dangerous condition.
- 366. The DRUG COMPANY DEFENDANTS knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of metoclopramide that caused the damages for which Plaintiff seeks recovery.
- 367. The reasonably foreseeable use of metoclopramide, that is ingestion as treatment for gastritis/gastroesophageal reflux on a long term basis, involved substantial dangers not readily recognizable by the ordinary physician who prescribed metoclopramide or the patient, like Plaintiff, who consumed metoclopramide.
- 368. The DRUG COMPANY DEFENDANTS knew that the metoclopramide was to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that metoclopramide was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.
- 369. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of metoclopramide, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.
- 370. These defects caused serious injuries to Plaintiff when the product was used in its intended and foreseeable manner, and in the manner recommended by the DRUG COMPANY DEFENDANTS or in a non-intended manner that was reasonably foreseeable.

BREACH OF EXPRESS WARRANTY BY WYETH AND SCHWARZ

- 371. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 372. Defendants Wyeth and Schwarz's concealment and failure to warn through promotional statements and product literature expressly warranted to Plaintiff that its drug Reglan, metoclopramide and/or metoclopramide HCl was safe and capable of treating gastrointestinal disorders, including diabetic gastroparesis, a long term chronic condition.
- 373. In response to these promises and express statements, Plaintiff and Plaintiff's physicians relied on such affirmations and warranties to Plaintiff through Plaintiff's physicians.
- 374. Reglan, metoclopramide and/or metoclopramide HCl do not conform to those express representations in light of recently discovered disclosures and information previously withheld by Wyeth and Schwarz. Wyeth and Schwarz's express warranty through its false statements failed to disclose and provide patient approval of the design, manufacturing and safety defects inherent in the drug.
- 375. Wyeth and Schwarz breached its warranty of Reglan, metoclopramide and/or metoclopramide HCl by continuing sales and marketing campaigns highlighting the safety of its drug, while it knew of the design, manufacturing and safety defects and risk of contracting a severe neurological disorder which was posed by the drug.
- 376. As a direct and proximate result of Wyeth and Schwarz's breach of its express warranty,

 Plaintiff suffered bodily and mental injury, harm, other compensable injury and economic losses, compensable through this Court.

COUNT 3

NEGLIGENCE AGAINST DRUG COMPANY DEFENDANTS

377. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this

- CASE 0:07-cv-03919-DWF-SER Document 1-1 Filed 09/07/07 Page 22 of 47 Complaint with the same force and effect as if fully set forth herein.
- 378. DRUG COMPANY DEFENDANTS had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of Reglan, metoclopramide and/or metoclopramide HCl to insure the safety of its drug and to insure that the consuming public, including the Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the safe use or non-use of this drug.
- DRUG COMPANY DEFENDANTS breach of its duties proximately caused damages to Plaintiff. As a direct and proximate cause of DRUG COMPANY DEFENDANTS conduct, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability. DRUG COMPANY DEFENDANTS breached their duty with the understanding customers and physicians would rely upon such actions when choosing DRUG COMPANY DEFENDANT'S drug.
- As manufacturers of prescription drug products, specifically Reglan, metoclopramide and/or metoclopramide HCl products, the DRUG COMPANY DEFENDANTS owed a duty toward foreseeable users of Reglan, metoclopramide and/or metoclopramide HCl products, including the Plaintiff, to exercise reasonable care to ensure that the Reglan, metoclopramide and/or metoclopramide HCl products they manufactured and/or distributed were reasonably safe for their ordinary and intended uses, and specifically, inter alias, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks inherent in such use.
- 381. Each of the DRUG COMPANY DEFENDANTS breached their duty, including the duty to assure that their products did not cause users to suffer from foreseeable unreasonably

dangerous side effects and serious health problems, to members of the public who were expected to use their Reglan, metoclopramide and/or metoclopramide HCl products, including the Plaintiff, by failing to exercise reasonable care in testing the products for their effects in ordinary and foreseeable uses, including long term use, and in disseminating to physicians information concerning the effects of the product which was accurate, not misleading, and otherwise adequate to enable to physicians to make informed choices concerning the reasonably safe use of the products.

- 382. DRUG COMPANY DEFENDANTS failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the drugs into the stream of interstate commerce in that DRUG COMPANY DEFENDANTS knew or should have known that the drugs created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.
- 383. The dangerous propensities of Reglan, metoclopramide and/or metoclopramide HCl products, as referenced above, were known or scientifically knowable, through appropriate research and testing, to the DRUG COMPANY DEFENDANTS at the time they distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for their patients, or their patients.
- As manufacturers of prescription drug products, specifically Reglan, metoclopramide and/or metoclopramide HCl products, the DRUG COMPANY DEFENDANTS owed a duty toward foreseeable users of Reglan, metoclopramide and/or metoclopramide HCl products, including the Plaintiff, to exercise reasonable care to ensure that the Reglan, metoclopramide and/or metoclopramide HCl products they manufactured and/or distributed were reasonably safe for their ordinary and intended uses, and specifically, inter alia, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the

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- 385. Each of the DRUG COMPANY DEFENDANTS breached their duty towards members of the public who were expected to use their Reglan, metoclopramide and/or metoclopramide HCl products, including the Plaintiff, by failing to exercise reasonable care in testing the products for their effects in ordinary and foreseeable uses, including long term use, and in disseminating to physicians information concerning the effects of the product which was accurate, not misleading, and otherwise adequate to enable to physicians to make informed choices concerning the reasonably safe use of the products.
- 386. The information the DRUG COMPANY DEFENDANTS disseminated to physicians concerning their Reglan, metoclopramide and/or metoclopramide HCl products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.
- 387. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, Reglan, metoclopramide and/or metoclopramide HCl, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by DRUG COMPANY DEFENDANTS through third parties or related entities.
- 388. At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and prepare for use and sell metoclopramide.
- 389. The DRUG COMPANY DEFENDANTS knew or should have known that use of metoclopramide created an unreasonable risk as a result of its design, testing, and/or manufacturing, including an unreasonable risk of central nervous system side effects, depression, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and/or interference with drug metabolism, especially in female patients diagnosed with

- diabetes mellitus and more particularly in patients who are poor metabolizers of metoclopramide.
- 390. The DRUG COMPANY DEFENDANTS were negligent, and breached duties owed to Plaintiff with respect to metoclopramide in one or more of the following respects:
 - (a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for long term use, they failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of metoclopramide and particularly with foreseeable long term use;
 - (b) They failed to conduct adequate testing;
 - (c) Despite knowledge of hazards, they failed to conduct adequate post-marketing surveillance to determine the safety of the product;
 - (d) Despite knowledge of hazards, they failed to adequately warn Plaintiff's physicians or Plaintiff that the use of metoclopramide could result in depression with suicidal ideation, akathesia, akinesia, tardive dyskinesia, tardive dystonia, visual disturbances and interferences with drug metabolism; and
 - (e) Despite the fact that the Drug Company Defendants knew or should have known that metoclopramide caused unreasonably dangerous side effects, they failed to adequately disclose the known or knowable risks associated with metoclopramide as set forth above; they willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.
- 391. As a result of the negligence of the DRUG COMPANY DEFENDANTS and their willful and wanton misconduct, metoclopramide was prescribed to Plaintiff for long term use and was used long term by Plaintiff, thereby causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this Complaint.
- 392. The negligence and the willful and wanton misconduct of the DRUG COMPANY DEFENDANTS was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer as previously described.
- 393. In the alternative, DRUG COMPANY DEFENDANTS acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding

patients and physicians would rely upon such statements when choosing DRUG COMPANY DEFENDANT'S drug. Furthermore, the economic damages and physical harm caused by DRUG COMPANY DEFENDANT'S conduct would not have occurred had DRUG COMPANY DEFENDANTS exercised the high degree of care imposed upon it and Plaintiff therefore plead the doctrine of *res ipsa loquitur*.

394. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

COUNT 4

MISREPRESENTATION BY OMISSION

- 395. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 396. DRUG COMPANY DEFENDANTS misrepresented the soundness and reliability of their drug to physicians and the general public through promotional and marketing campaigns. It misrepresented that Reglan, metoclopramide and/or metoclopramide HCl was safe and/or effective when used as instructed, when, in fact, it was dangerous to the health of patients.

 DRUG COMPANY DEFENDANTS continued these misrepresentations for an extended period of time, without disclosing material information.
- 397. DRUG COMPANY DEFENDANTS took advantage of the limited opportunity Plaintiff had to discover DRUG COMPANY DEFENDANTS strategic and intentional concealment of the design, manufacturing and safety defects in Reglan, metoclopramide and/or metoclopramide HCl.
- 398. At the time DRUG COMPANY DEFENDANTS promoted the drug at issue as safe and/or effective, DRUG COMPANY DEFENDANTS did not have adequate proof upon which to base such representations, and in fact, knew or should have known that drug was dangerous.

- 399. DRUG COMPANY DEFENDANTS concealed these design and manufacturing defects from the public by withholding information pertaining to the inherent design, manufacturing and safety defects and high risks of a severe and permanent neurological condition relating to DRUG COMPANY DEFENDANTS Reglan, metoclopramide and/or metoclopramide HCl drug and presenting the drug as sound and reliable.
- 400. DRUG COMPANY DEFENDANTS intentional misrepresentations and omissions were made willfully, wantonly or recklessly to the Plaintiff to induce purchase of DRUG COMPANY DEFENDANTS Reglan, metoclopramide and/or metoclopramide HCl drug over other drugs on the market.
- 401. DRUG COMPANY DEFENDANTS knew or should have known of the high risk Plaintiff would encounter by unwittingly agreeing to ingest DRUG COMPANY DEFENDANTS defective drug.
- 402. Defendants failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan, metoclopramide and/or metoclopramide HCl and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physician, and the public in general.
- 403. Defendants made the aforesaid representations in the course of Defendants business as designers, manufacturers, and distributors of the drug at issue despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that, without such information, it could not accurately make the aforesaid representations.
- 404. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff and/or Plaintiff's physicians to rely upon such representations.
- 405. Said representations were made with the intent to defraud and deceive Plaintiff and/or Plaintiff's physicians and with the intent to induce Plaintiff and/or Plaintiff's physicians to

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- rely upon the statements and use of Reglan, metoclopramide and/or metoclopramide HCl.
- 406. Plaintiff and/or Plaintiff's physicians, at the time the representations were made, were unaware of their falsity and believed them to be true. In reasonable reliance thereon by Plaintiff and/or Plaintiff's physicians used Reglan, metoclopramide and/or metoclopramide HCl, and as a result, Plaintiff has suffered, and will continue to suffer, injury, harm and economic loss alleged herein.
- 407. As a direct and proximate result of reliance upon DRUG COMPANY DEFENDANTS misrepresentations, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

NEGLIGENCE

AS AGAINST DEFENDANT WYETH

- 408. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 409. As set forth above, Wyeth and its predecessors falsely and fraudulently represented to Plaintiff's physicians, and through them to Plaintiff and members of the general public, that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux and that central nervous system side effects and extrapyramidal symptoms were comparatively rare. These representations were, in fact, false. The true facts were that Reglan/metoclopramide was not safe for that purpose and was, in fact, dangerous to the health and body of Plaintiff.
- 410. Wyeth and its predecessors made other representations about the safety and efficacy of Reglan/metoclopramide, and its minimal side effects all as set forth above and incorporated here by reference.

- These representations were in fact, false. The true facts were that Reglan/metoclopramide causes central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented, and Wyeth and its predecessors did not disclose or warn physicians about the actual prevalence of known side effects of Reglan/metoclopramide, particularly when Reglan/metoclopramide is used on a long term basis or when used in patients who are poor metabolizers of metoclopramide, all of which were foreseeable. Wyeth and its predecessors misrepresented the safety of Reglan/metoclopramide and withheld warnings of the known side effects of Reglan/metoclopramide when used as commonly prescribed by physicians as specifically required by 21 C.F.R. § 201.128.
- When Wyeth and its predecessors made these representations, they knew that they were false.

 Wyeth made these representations with the intent to defraud and deceive Plaintiff's physicians and through them to defraud and deceive Plaintiff and with the intent to induce Plaintiff and Plaintiff physicians to act in the manner alleged in this Complaint that is to use Reglan/metoclopramide as pharmaceutical treatment for gastritis/gastroesophageal reflux for a period of time that far exceeded the FDA's approved indicated duration of use.
- 413. At the time Wyeth and its predecessors made the above described representations and at the time Plaintiff and Plaintiff physicians took the actions alleged in this Complaint, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true. In reliance upon the representations, Plaintiff's physicians were induced to and did prescribe Reglan/metoclopramide as described in this Complaint and Plaintiff did use Reglan/metoclopramide as described in this Complaint.
- 414. If Plaintiff's physicians had known the actual facts they would not have prescribed Reglan/metoclopramide in the manner that they prescribed it and Plaintiff would not have taken Reglan/metoclopramide in the way that it was prescribed.

- 415. The reliance of Plaintiff and Plaintiff's physicians upon the representations of Wyeth and its predecessors was justified because the representations were made by individuals and entities that appeared to be in the position to know the true facts.
- 416. As a proximate result of the fraud and deceit of Wyeth and its predecessors, Plaintiff sustained the injuries and damages described in this Complaint.
- 417. In doing the acts alleged in this Complaint, Wyeth and its predecessors acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Wyeth and others from engaging in similar conduct in the future. This wrongful conduct was done with the advance knowledge, authorization, or ratification of an officer, director, or managing agent of each of Wyeth and its predecessors.

NEGLIGENT MISREPRESENTATION

- 418. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 419. DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ PHARMA owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan, metoclopramide and/or metoclopramide HCl, to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.
- 420. DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ PHARMA disseminated to physicians, through package inserts, the publication of a PDR monograph, and otherwise, information concerning the properties and effects of Reglan, metoclopramide and/or metoclopramide HCl, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

- 421. It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act and the laws and regulations of the State of Minnesota to encourage the availability of cheaper, generic drug products that are therapeutically equivalent name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.
- PHARMA, as prescription drug manufacturers and/or distributors, knew or ought to have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limited exceptions, with a generic drug product that is therapeutically equivalent to the name brand drug product.
- PHARMA, as prescription drug manufacturers and/or distributors, knew or ought to have realized that the manufacturers and/or distributors of generic products, as a custom, to either ensure or give the impression that the information contained in the package inserts accompanying their own generic prescription drug products is accurate, complete, not misleading, and otherwise adequate, typically and simply copy verbatim, for those package inserts, the therapeutically relevant content of the package insert for the name brand prescription drug product, for which the generic products are therapeutic equivalents; and, further, that the manufacturers of the counterpart generic products typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.
- 424. DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ PHARMA, knew or ought to have realized that physicians, to obtain basic information about the properties and effects of a drug or drug product that is available in both name brand and generic formulations, commonly and typically consult the information disseminated by the

manufacturer/distributor of name brand product, in PDR monographs or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients, whether by brand name or generic name, and that the patients are likely to receive and ingest, per those prescriptions, one or more generic products that are therapeutically equivalent to the name brand product.

- DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using Reglan, metoclopramide and/or metoclopramide HCl products, whether name brand or generic or either, and in writing prescriptions for either "Reglan" or "metoclopramide," would rely upon information disseminated to them by the manufacturer of the name brand drug product, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan, metoclopramide and/or metoclopramide HCl products, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan, metoclopramide and/or metoclopramide HCl products.
- 426. DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ, knew or ought to have realized that patients receiving prescriptions for Reglan or generic Reglan, metoclopramide and/or metoclopramide HCl written in reliance upon information they disseminated as the manufacturer/distributor of Reglan, the name brand Reglan product, would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.
- 427. DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., AND SCHWARZ, and its predecessors in interest, failed to exercise reasonable care to ensure that the information they disseminated to physicians concerning the properties and effects of Reglan, metoclopramide and/or metoclopramide HCl and Reglan was accurate and not misleading, and as a result

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 - disseminated information to physicians that was negligently and materially inaccurate, misleading, and false.
- As a proximate and foreseeable result of this negligence on the part of DRUG COMPANY DEFENDANTS, WYETH, WYETH, INC., and SCHWARZ, the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon the negligently inaccurate, misleading, and false information disseminated by said Defendants, and their predecessors in interest, and believing the information to be true, prescribed for the Plaintiff the use of Reglan, metoclopramide and/or metoclopramide HCl for a prolonged and unwarranted period of time and Plaintiff ingested, per those prescriptions, Reglan, metoclopramide and/or metoclopramide HCl products, leading to Plaintiff's toxic overexposure to Reglan, metoclopramide and/or metoclopramide HCl.

NEGLIGENT MISREPRESENTATION

AS AGAINST DEFENDANT WYETH AND DEFENDANT SCHWARZ

- 429. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 430. Wyeth and Schwarz had actual knowledge of facts which demonstrated that representations in the Reglan package insert, the PDR monograph for Reglan and literature that they distributed concerning Reglan/metoclopramide to physicians were false and misleading. Wyeth and Schwarz had an absolute duty to disclose the true facts regarding the safety of Reglan to physicians and their patients, pharmacists, and the generic metoclopramide industry, which they negligently failed to do. Furthermore, Wyeth and Schwarz had a duty to ensure that they had a reasonable basis for making the representations described above, to exercise reasonable care in making those representations, to accurately make those

representations, and to not make misrepresentations, all of which they negligently failed to do.

- Wyeth and Schwarz and was exclusively known by them. As part of their business and in the furtherance of their own interests, Wyeth and Schwarz disseminated information regarding metoclopramide to physicians and their patients, pharmacists and the generic metoclopramide industry and did so knowing that the safety of metoclopramide users depended on the accuracy of that information. Further, Wyeth and Schwarz knew and expected that recipients of that information would rely on it, that they would take action based upon it, that individuals would be put in peril by such action and that those individuals would suffer physical harm as a result.
- 432. Wyeth and Schwarz expressly and/or impliedly represented to Plaintiff, Plaintiff's physicians, pharmacists, the generic metoclopramide industry and members of the general public that Reglan/metoclopramide was safe for use to treat nausea and/or esophageal reflux for durations of use that exceeded the 12 week duration indicated in Wyeth and Schwarz's package inserts and in the PDR. The representations by Wyeth and Schwarz and the lack of them were, in fact, false. The true facts were that Reglan/metoclopramide was not safe for use in the manner in which it was prescribed and was, in fact, dangerous to the health and body of Plaintiff.
- 433. Wyeth and Schwarz made the above described representations with no reasonable grounds for believing them to be true. Wyeth and Schwarz did not have accurate or sufficient information concerning these representations and they failed to exercise reasonable care both in ascertaining the accuracy of the information contained in those representations and in communicating the information. Further, Wyeth and Schwarz were aware that without such information they could not accurately make the above described representations.

434. The above misrepresentations or omissions were made to Plaintiff's physicians, pharmacists, the generic pharmaceutical industry and the general public, all of whom justifiably and foreseeably relied on those representations or omissions. Plaintiff would not have suffered Plaintiff injuries but for the above misrepresentations or omissions. Wyeth and Schwarz's misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

COUNT 8

FRAUD BY CONCEALMENT

- 435. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- The DRUG COMPANY DEFENDANTS, with the intention of deceiving physicians and 436. their patients, and to induce physicians to prescribe, and their patients to ingest, Reglan, metoclopramide and/or metoclopramide HCl products for prolonged periods of time, informed physicians, through package inserts and otherwise, that exposure to Reglan, metoclopramide and/or metoclopramide HCl can lead to Tardive Dyskinesia and other ESP, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than twelve (12) weeks "cannot be recommended," but knowingly concealed from the physicians material facts bearing on the interpretation of those disclosures, including the fact that earlier false information, disseminated by A.H. ROBINS COMPANY, and representing long term Reglan, metoclopramide and/or metoclopramide HCl therapy to be reasonably safe, was unscientific and false; that Reglan, metoclopramide and/or metoclopramide HCl is a neuroleptic agent and dopamine antagonist, which can be expected to lead to Tardive Dyskinesia and other ESP with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs; that epidemiological studies have consistently confirmed this expectation; and that the treatment of chronic or

intermittent gastroesophageal reflux and/or diabetic gastroporesis, and/or other gastric disorders with Reglan, metoclopramide and/or metoclopramide HCl products for longer than 12 weeks is unlikely to be reasonably safe.

- 437. The Plaintiff's physician, in reliance upon the information disseminated by the DRUG COMPANY DEFENDANTS, and without knowledge of the undisclosed and knowingly concealed facts, determined that the benefits of prolonged Reglan, metoclopramide and/or metoclopramide HCl therapy outweighed the risks for their patient, the Plaintiff, and prescribed a prolonged course of therapy for Plaintiff with Reglan, metoclopramide and/or metoclopramide HCl products.
- 438. As a proximate and foreseeable result of this knowing and fraudulent concealment of material facts on the part of the DRUG COMPANY DEFENDANTS, Plaintiff suffered grievous bodily injury and consequent economic and other loss when Plaintiff's physician, in reliance upon the information disseminated by the DRUG COMPANY DEFENDANTS, and in ignorance of the facts concealed from them in those disseminations, prescribed for the Plaintiff the use of Reglan, metoclopramide and/or metoclopramide HCl for a prolonged and unwarranted period of time and Plaintiff ingested, per those prescriptions, Reglan, metoclopramide and/or metoclopramide to Plaintiff's toxic overexposure to Reglan, metoclopramide and/or metoclopramide HCl.

COUNT 9

VIOLATION OF MINNESOTA CONSUMER PROTECTION ACT

- 439. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 440. By reason of the conduct as alleged herein, DRUG COMPANY DEFENDANTS violated the Minnesota Consumer Protection Act, by knowingly and intentionally inducing Plaintiff to use the drugs through the use of false and/or misleading advertising, representations and

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statements. The products failed to perform as represented and advertised, and in fact were unsafe.

- 441. The DRUG COMPANY DEFENDANTS induced the Plaintiff and Plaintiff's physician, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or prescribe Reglan, metoclopramide and/or metoclopramide HCl products which they manufactured and/or distributed and sold, all in violation of the Minnesota Consumer Protection Act which proscribes, among other things:
 - a. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that have the capacity, tendency or effect of deceiving or misleading consumers;
 - b. Engaging in unfair trade practices as defined in the statute by making representations that their products had an approval, characteristic, ingredient, use or benefit which they did not have, including but not limited to statements concerning the health consequences of the use of drugs;
 - c. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceive or tend to deceive, including but not limited to, facts relating to the health consequences of the use of these drugs; and
 - d. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the drugs.
- 442. As a direct and proximate result of DRUG COMPANY DEFENDANTS statutory violations, plaintiff used the drugs as prescribed, which Plaintiff would not have used had DRUG COMPANY DEFENDANTS not issued false and/or misleading advertising, representations

- CASE 0:07-cv-03919-DWF-SER Document 1-1 Filed 09/07/07 Page 38 of 47 and statements.
- 443. By reason of such violations and pursuant to the laws and regulations of this state, Plaintiff is entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the products; together with any and all actual damages recoverable under the law including, but not limited to, past medical expenses, past wage loss, past pain, suffering, disability and emotional distress.
- 444. In addition, Plaintiff is entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.
- 445. Defendant WYETH (including A.H. Robins Company, Inc., prior to its merger into WYETH, and as WYETH thereafter) has marketed Reglan to physicians in a manner calculated to increase sales of the drug and resultant profits to the drug company at the expense of and in conscious disregard for the health and safety of those who, through over-prescription of the drug at excessive dosage and/or for excessive periods of time and/or for patients for whom safer effective alternative treatments existed, consequently develop Tardive Dyskinesia and other extrapyramidal symptoms (EPS).
- 446. In doing the wrongful acts alleged in this Complaint, WYETH, WYETH, INC., AND SCHWARZ, acted with oppression, fraud, and malice, evincing a willful, wanton, and conscious disregard for the rights, health, and safety of patients, including the Plaintiff, who would be expected to be induced, by that conduct, to ingest unwarranted amounts of Reglan, metoclopramide and/or metoclopramide HCl for prolonged and unwarranted periods of time, leading to grievous, debilitating, and potentially permanent personal injury.
- 447. Some or all of the other DRUG COMPANY DEFENDANTS, as a result of their participation as DRUG COMPANY DEFENDANTS in previous litigation concerning Reglan and other Reglan, metoclopramide and/or metoclopramide HCl products, received

- clear notice of WYETH'S suppression of important safety information concerning Reglan, metoclopramide and/or metoclopramide HCl and their products, yet despite this notice chose to ignore the information and join consciously in the suppression.
- 448. The conduct of the DRUG COMPANY DEFENDANTS, and each of them, undertaken consciously and with notice, evinces a willful, wanton, and conscious disregard for the rights, healthy, and safety of patients, including the Plaintiff, who would be expected to be induced, by that conduct, to ingest unwarranted amounts of Reglan, metoclopramide and/or metoclopramide HCl for prolonged and unwarranted periods of time, leading to grievous, debilitating, and potentially permanent personal injury.
- As a direct and proximate result of the wrongful acts of the DRUG COMPANY DEFENDANTS Plaintiff developed severe Tardive Dyskinesia, suffered irreparable nerve damage and bodily injury, suffered and will continue to suffer great pain of body and mind, suffered and will continue to suffer great embarrassment and humiliation, suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity, has incurred and will continue to incur great expenses for medical treatment of Plaintiff's injuries, has suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

FRAUD BY CONCEALMENT

AS AGAINST DEFENDANT WYETH AND DEFENDANT SCHWARZ

- 450. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 451. At all times mentioned in this Complaint, Wyeth and its predecessors had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians the true facts concerning Reglan/ metoclopramide, that is, that Reglan/metoclopramide was dangerous and defective

and how likely it was to cause serous consequences to users, including injuries as described in this Complaint, and the true level of risk involved in prescribing Reglan/metoclopramide for the purposes indicated. Wyeth and its predecessors made the affirmative representations set forth above to Plaintiff, Plaintiff's prescribing physicians, and the general public prior to the day Plaintiff was first prescribed and used Reglan/ metoclopramide while concealing the material facts set forth below.

- 452. At all times mentioned in this Complaint, Wyeth and its predecessors had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians the true facts concerning Reglan/ metoclopramide that is that long term use and exposure could cause central nervous system side effects, depression with suicidal ideation, akathesia, akinesia, tardive dyskinesia and tardive dystonia. At all times mentioned in this Complaint, Wyeth and its predecessors intentionally, willfully and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from Plaintiff, with the intent to defraud as alleged in this Complaint.
- 453. At all times mentioned in this Complaint, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above. Had they been aware of those facts, they would not have acted as they did, that is, would not have utilized Reglan/metoclopramide in the treatment of Plaintiff's gastritis/gastroesophageal reflux for periods of time that exceeded 12 weeks duration.
- 454. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff was prescribed and took Reglan/metoclopramide and subsequently became ill, thereby sustaining the injuries and damages as set forth in this Complaint.
- 455. In doing the acts alleged in this Complaint, Wyeth and its predecessors acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to Wyeth's wealth, and sufficiently large

to be an example to others and to deter Wyeth and others from engaging in similar conduct in the future.

COUNT 11

BREACH OF IMPLIED WARRANTIES

- 456. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 457. The DRUG COMPANY DEFENDANTS knew that most physicians who prescribed Reglan, metoclopramide and/or metoclopramide HCl were not aware the drug is a dopamine antagonist and/or a neuroleptic agent, which is just as likely to cause serious extrapyramidal side effects as other dopamine antagonists and/or other neuroleptic drugs. The DRUG COMPANY DEFENDANTS also knew that the risks of potentially irreversible neurological side effects when Reglan, metoclopramide and/or metoclopramide HCl is used long term were much greater than most physicians realized. By failing to give adequate warnings about the dopamine antagonist and/or neuroleptic properties of Reglan, metoclopramide and/or metoclopramide HCl and the risk of long term use that is associated with those properties, the DRUG COMPANY DEFENDANTS breached implied warranties of merchantability and fitness for the ordinary use of Reglan, metoclopramide and/or metoclopramide HCl.
- 458. At all times mentioned in this Complaint, the DRUG COMPANY DEFENDANTS manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold Reglan, metoclopramide and/or metoclopramide HCl and prior to the time it was used by Plaintiff, the DRUG COMPANY DEFENDANTS impliedly warranted to Plaintiff and to Plaintiff's physicians that the product was of merchantable quality and safe and fit for the use for which it was intended.
- 459. Plaintiff relied on the skill and judgment of the DRUG COMPANY DEFENDANTS in using Reglan, metoclopramide and/or metoclopramide HCl.

- 460. Reglan, metoclopramide and/or metoclopramide HCl was unsafe and unfit for its intended use, nor was it of merchantable quality, as warranted by the DRUG COMPANY DEFENDANTS, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. Reglan, metoclopramide and/or metoclopramide HCl was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, Reglan, metoclopramide and/or metoclopramide HCl proximately caused Plaintiff's illness.
- 461. After Plaintiff was made aware of Plaintiff's injuries as a result of Reglan, metoclopramide and/or metoclopramide HCl, notice was duly given to the DRUG COMPANY DEFENDANTS of the breach of the above described warranties.

STRICT JOINT AND SEVERAL LIABILITY

- 462. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 463. By virtue of their individual and collective acts and omissions, Defendants are jointly and severally liable to Plaintiff as such acts and omissions have proximately caused Plaintiff to suffer a single indivisible injury for which each Defendant is responsible.

COUNT 13

CONSTRUCTIVE FRAUD

- 464. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 465. DRUG COMPANY DEFENDANTS, while in possession of unique and pertinent information involving the safety and reliability of Reglan, metoclopramide and/or

metoclopramide HCl as sound and failed to warn of the drugs inherent design, safety and manufacturing defects. DRUG COMPANY DEFENDANTS suppressed this information and continued sales and marketing of their drug to the general public. DRUG COMPANY DEFENDANTS knew or should have known Plaintiff had no means, other than DRUG COMPANY DEFENDANTS full, accurate, and objective disclosure, of obtaining the relevant information.

- 466. Through its unique knowledge and expertise regarding the affected nature of Reglan, metoclopramide and/or metoclopramide HCl and through its statements to physicians and their patients in advertisement, promotional materials, and other communications, DRUG COMPANY DEFENDANTS professed and affirmed to Plaintiff its knowledge of the truth of the representation that the drug at issue was safe for its intended use and was free from design, safety and manufacturing defects.
- 467. DRUG COMPANY DEFENDANTS misrepresentations and omissions were made intentionally to induce Plaintiff to purchase DRUG COMPANY DEFENDANTS drug in order to reap the high profit margin relating to DRUG COMPANY DEFENDANTS
- 468. DRUG COMPANY DEFENDANTS conduct took unconscionable advantage of its dominant position of knowledge, engaging in constructive fraud in its relationship with Plaintiff. Misled by this veil of fraud, Plaintiff reasonably relied on DRUG COMPANY DEFENDANTS representations.
- 469. As a result, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

COUNT 14

INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

470. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this

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 - Complaint with the same force and effect as if fully set forth herein.
- 471. Through intentional, reckless, and extreme conduct DRUG COMPANY DEFENDANTS knowingly denied Plaintiff adequate opportunity in measuring the level of risk related to DRUG COMPANY DEFENDANTS Reglan, metoclopramide and/or metoclopramide HCl drug. By withholding information of known design and manufacturing defects and concealing those fatal problems, DRUG COMPANY DEFENDANTS created a false sense of security for Plaintiff, who assumed reasonable safety with DRUG COMPANY DEFENDANTS drug Reglan, metoclopramide and/or metoclopramide HCl.
- 472. DRUG COMPANY DEFENDANTS conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.
- 473. The injuries described above entitle Plaintiff to compensatory damages and equitable and declaratory relief, along with all appropriate damages according to proof.

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

- 474. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.
- 475. DRUG COMPANY DEFENDANTS intentionally and willfully failed to disclose or warn of the inherent risks and defects to its physicians and patients. DRUG COMPANY DEFENDANTS enforced its negligent conduct through manufacturing, marketing, and selling its defective drug to Plaintiff, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety, and efficacy of the drug.

- 476. DRUG COMPANY DEFENDANTS willful conduct inflicted Plaintiff with severe emotional distress through Plaintiff=s subsequent illness, and permanent disability resulting from Reglan, metoclopramide and/or metoclopramide HCl.
- 477. DRUG COMPANY DEFENDANTS conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of the drug caused Plaintiff severe emotional distress.
- 478. As a direct result of DRUG COMPANY DEFENDANTS careless and negligent conduct,
 Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged
 herein, including a permanent and substantial physical disability, and expenses attributable to
 this disability.

VI. DAMAGES

- 479. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff ingested Reglan, which was causally related to and contributed to Plaintiff's development of the permanent neurological disorder known as Tardive Dyskinesia.
- 480. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff has suffered extreme emotional distress, anguish, physical and mental suffering, loss of the ability to control Plaintiff's facial expressions, mouth, tongue and jaw, and has rendered Plaintiff's physically incapacitated.
- 481. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiff experiences extreme embarrassment, shame, anguish, anxiety, and has a sustained a loss of enjoyment of life.
- 482. Plaintiff seeks the recovery for past and future special damages, which includes medication, doctor, rehabilitation, therapy, and other assisted living and nursing care and Plaintiff also seeks general damages in the amount to be determined for the wrongful conduct of each separate and individual Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants as follows:

- 483. For judgment for damages sufficient to compensate for damages in excess of \$75,000.00, including but not limited to past, present, and future economic expenditures in connection with DRUG COMPANY DEFENDANTS Reglan, metoclopramide and/or metoclopramide HCl drug;
- 484. For compensatory damages according to proof;
- For all applicable statutory remedies provided by law in Minnesota that assert liability for DRUG COMPANY DEFENDANTS wrongdoings and improper conduct;
- 486. For a disgorgement of profits;
- 487. For prejudgment interest, as permitted by law;
- 488. For reasonable costs, including attorneys fees as permitted by law; and
- 489. For all other just and proper relief.

Plaintiff seeks a trial by jury on all issues.

Respectfully Submitted,

GOLDENBERG & JOHNSON, PLLC

By_

Michael K. Johnson (#258696) 33 South Sixth Street Suite 4530 Minneapolis, Minnesota 55402 (612) 333-4662 Attorneys for Plaintiff

And, Of Counsel

McGLYNN, GLISSON & KOCH

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ACKNOWLEDGMENT

The undersigned hereby acknowledges that costs, dis	sbursements, and reasonable
attorneys and witness fees may be awarded pursuant to Mini	y. Stat. \$549.21, Subd. 2, to the
parties against whom the allegations in this pleading are ass	erted.

Dated: 9/7/07

By______Michael K. Johnson (#258696) Goldenberg & Johnson, PLLC 33 South Sixth Street Suite 4530 Minneapolis, Minnesota 55402 (612) 333-4662

And, Of Counsel

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